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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,475	11/20/2001	Vladislav Olchanski	58367.000003	2706

7590 11/12/2008

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EXAMINER	
TANG, KAREN C	

ART UNIT	PAPER NUMBER
2451	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/996,475	OLCHANSKI ET AL.	
	Examiner	Art Unit	
	KAREN C. TANG	2451	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/12/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

- This action is responsive to the amendment and remarks file on 08/12/08.
- Claims 1-21, 23-30 are presented for further examination.
- Claims 1, 2, 6, 8, 9, 11, 12, 16, 17, 19, 21, and 23-25

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 08/12/08 have been fully considered but they are not persuasive.

Affidavit

2. The affidavit filed on 05/25/07 under 37 CFR 1.131 *again*, has been considered but is ineffective to overcome the Menzie et al. reference.

The declaration filed on 05/25/07 fails to provide evidence to support the indicated claim of conception prior to the effective date of the Menzie reference. The evident is not enough to satisfy issues of diligence or conception reduction to practice or an actual reduction to practice.

3. Applicant is attempt to prove the invention by showing conception before May 15, 2000 (the effective data of Menzie) before that date until Nov 20, 2001, the date of filing of this application.

4. The evidence submitted is *insufficient* to establish a conception of the invention prior to the effective date of the Menzie reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The exhibit does not demonstrate the

evidence or proof in showing that the claimed conception took place. *Applicant has not yet support each of claim element with the affidavit to demonstrate conception*. Applicant must point out where each claimed limitation is according to the affidavit on record.

Applicant has provided the same 23 pages from the affidavit for mapping all the limitations without explaining how these pages are relevant to the claim limitations. Applicant needs to map the limitation by point to a specific page and line number on the affidavit in order to demonstrate the conception. Applicant needs to also apply the mapping on all the dependent claims, or else the depending claims cannot receive the benefit of priority date supported by the affidavit.

5. Applicant has not demonstrated the reasonable diligence from the period of **May 15, 2000, to November 21, 2000**.

6. Applicant has not demonstrated the reasonable diligence from the period of **November 30, 1998, to March 31, 1999**.

7. Applicant has not demonstrated the reasonable diligence from the period of **March 1999, to July 2000**.

8. Applicant has not demonstrated the reasonable diligence from the period of **August 4, 1999, to September 24, 2000**.

2138.06 [R-1] "Reasonable Diligence"

The diligence of 35 U.S.C. 102(g) relates to rea-sonable "attorney-diligence" and "engineering-diligence" (*Keizer v. Bradley*, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959)), which does not require that "an inventor or his attorney ... drop all other work and concentrate on the particular invention involved...." *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974).

CRITICAL PERIOD FOR ESTABLISHING DILIGENCE BETWEEN ONE WHO WAS FIRST TO CONCEIVE BUT LATER TO REDUCE TO PRACTICE THE INVENTION

The critical period for diligence for a first conceiver but second reducer begins not at the time of conception of the first conceiver but just prior to the entry in the field of the party who was first to reduce to practice and continues until the first conceiver reduces to practice. *Hull v. Davenport*, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937) ("lack of diligence from the time of conception to the time immediately preceding the conception date of the second conceiver is not regarded as of importance except as it may have a bearing upon his subsequent acts"). What serves as the entry date into the field of a first reducer is dependent upon what is being relied on by the first reducer, e.g., conception plus reasonable diligence to reduction to practice (*Fritsch v. Lin*, 21 USPQ2d 1731, 1734 (Bd. Pat. App. & Inter. 1991), *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974)); an actual reduction to practice or a constructive reduction to practice by the filing of either a U.S. application (*Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975)) or reliance upon priority under 35 U.S.C. 119 of a foreign application (*Justus v. Appenzeller*, 177 USPQ 332, 339 (Bd. Pat. Inter. 1971) (chain of priorities under 35 U.S.C. 119 and 120, priority under 35 U.S.C. 119 denied for failure to supply certified copy of the foreign application during pendency of the application filed within the twelfth month)).

THE ENTIRE PERIOD DURING WHICH DILIGENCE IS REQUIRED MUST BE ACCOUNTED FOR BY EITHER AFFIRMATIVE ACTS OR ACCEPTABLE EXCUSES

An applicant must account for the entire period during which diligence is required. *Gould*

v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); *Fitzgerald v. Arbib*, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be embodied in some structure other than a mere drawing.); *Kendall v. Searles*, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) (Diligence requires that applicants must be specific as to dates and facts.).

The period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses. *Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975); *Rieser v. Williams*, 225 F.2d 419, 423, 118 USPQ 96, 100 (CCPA 1958) (Being last to reduce to practice, party cannot prevail unless he has shown that he was first to conceive and that he exercised reasonable diligence during the critical period from just prior to opponent's entry into the field); *Griffith v. Kanamaru*, 816 F.2d 624, 2 USPQ2d 1361 (Fed. Cir. 1987) (Court generally reviewed cases on excuses for inactivity including vacation extended by ill health and daily job demands, and held lack of university funding and personnel are not acceptable excuses.); *Litchfield v. Eigen*, 535 F.2d 72, 190 USPQ 113 (CCPA 1976) (budgetary limits and availability of animals for testing not sufficiently described); *Morway v. Bondi*, 203 F.2d 741, 749, 97 USPQ 318, 323 (CCPA 1953) (voluntarily laying aside inventive concept in pursuit of other projects is generally not an acceptable excuse although there may be circumstances creating exceptions); *Anderson v. Crowther*, 152 USPQ 504, 512 (Bd. Pat. Inter. 1965) (preparation of routine periodic reports covering all accomplishments of the laboratory insufficient to show diligence); *Wu v. Jucker*, 167 USPQ 467, 472-73 (Bd. Pat. Inter. 1968) (applicant improperly allowed test data sheets to accumulate to a sufficient amount to justify interfering with equipment then in use on another project);

Tucker v. Natta, 171 USPQ 494,498 (Bd. Pat. Inter. 1971) ("[a]ctivity directed toward the reduction to practice of a genus does not establish, *prima facie*, diligence toward the reduction to practice of a species embraced by said genus"); *Justus v. Appenzeller*, 177 USPQ 332, 340-1 (Bd. Pat. Inter. 1971) (Although it is possible that patentee could have reduced the invention to practice in a shorter time by relying on stock items rather than by designing a particular piece of hardware, patentee exercised reasonable diligence to secure the required hardware to actually reduce the invention to practice. "[I]n deciding the question of diligence it is immaterial that the inventor may not have taken the expeditious course....").

WORK RELIED UPON TO SHOW REASONABLE DILIGENCE MUST BE DIRECTLY RELATED TO THE REDUCTION TO PRACTICE

The work relied upon to show reasonable diligence must be directly related to the reduction to practice of the invention in issue. *Naber v. Cricchi*, 567 F.2d 382, 384, 196 USPQ 294, 296 (CCPA 1977), *cert. denied*, 439 U.S. 826 (1978). >See also *Scott v. Koyama*, 281 F.3d 1243, 1248-49, 61 USPQ2d 1856, 1859 (Fed. Cir. 2002) (Activities directed at building a plant to practice the claimed process of producing tetrafluoroethane on a large scale constituted efforts toward actual reduction to practice, and thus were evidence of diligence. The court distinguished cases where diligence was not found because inventors either discontinued development or failed to complete the invention while pursuing financing or other commercial activity.); *In re Jolley*, 308 F.3d 1317, 1326-27, 64 USPQ2d 1901, 1908-09 (Fed. Cir. 2002) (diligence found based on research and procurement activities related to the subject matter of the interference

count).< "[U]nder some circumstances an inventor should also be able to rely on work on closely related inventions as support for diligence toward the reduction to practice on an invention in issue." *Ginos v. Nedelec*, 220 USPQ 831, 836 (Bd. Pat. Inter. 1983) (work on other closely related compounds that were considered to be part of the same invention and which were included as part of a grandparent application). "The work relied upon must be directed to attaining a reduction to practice of the subject matter of the counts. It is not sufficient that the activity relied on concerns related subject matter." *Gunn v. Bosch*, 181 USPQ 758, 761 (Bd. Pat. Inter. 1973) (An actual reduction to practice of the invention at issue which occurred when the inventor was working on a different invention "was fortuitous, and not the result of a continuous intent or effort to reduce to practice the invention here in issue. Such fortuitousness is inconsistent with the exercise of diligence toward reduction to practice of that invention." 181 USPQ at 761. Furthermore, evidence drawn towards work on improvement of samples or specimens generally already in use at the time of conception that are but one element of the oscillator circuit of the count does not show diligence towards the construction and testing of the overall combination.); *Broos v. Barton*, 142 F.2d 690, 691, 61 USPQ 447, 448 (CCPA 1944) (preparation of application in U.S. for foreign filing constitutes diligence); *De Solms v. Schoenwald*, 15 USPQ2d 1507 (Bd. Pat. App. & Inter. 1990) (principles of diligence must be given to inventor's circumstances including skill and time; requirement of corroboration applies only to testimony of inventor); *Huelster v. Reiter*, 168 F.2d 542, 78 USPQ 82 (CCPA 1948) (if inventor was not able to make an actual reduction to practice of the invention, he must also show why he was not able to constructively reduce the invention to practice by the filing of an application).

DILIGENCE REQUIRED IN PREPARING AND FILING PATENT APPLICATION

The diligence of attorney in preparing and filing patent application inures to the benefit of the inventor. Conception was established at least as early as the date a draft of a patent application was finished by a patent attorney on behalf of the inventor. Conception is less a matter of signature than it is one of disclosure. Attorney does not prepare a patent application on behalf of particular named persons, but on behalf of the true inventive entity. Six days to execute and file application is acceptable. *Haskell v. Coleburne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982). See also *Bey v. Kollonitsch*, 866 F.2d 1024, 231 USPQ 967 (Fed. Cir. 1986) (Reasonable diligence is all that is required of the attorney. Reasonable diligence is established if attorney worked reasonably hard on the application during the continuous critical period. If the attorney has a reasonable backlog of unrelated cases which he takes up in chronological order and carries out expeditiously, that is sufficient. Work on a related case(s) that contributed substantially to the ultimate preparation of an application can be credited as diligence.).

Under 37 CFR 1.131, the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive (i.e., filing a United States patent application). Note, therefore, that only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" is not relevant to an affidavit or declaration under 37 CFR 1.131. See *Ex parte Merz*, 75 USPQ 296 (Bd. App. 1947). Form paragraph 7.62 (reproduced in MPEP § 715) may be used to respond to a 37 CFR 1.131 affidavit where diligence is lacking.

9. The evidence submitted is insufficient to establish diligence from a date of conception to an actual reduction to practice. There is no information provided in the exhibits explicitly demonstrate diligence applied to reduce the method to practice.

10. The included Declaration fails to properly describe the events/dates between alleged conception (prior to May 15, 2000) and indicated Actual Reduction to Practice (November 21, 2001). Applicant's sole evident that demonstrate the diligent are the marketing agreement dated back in July 7, 2000, and a letter dated back in September 24, 2000, which indicates a "final

documentation", which did not particular indicate what documentation could it be. Not a single act in the affidavits had demonstrated during the critical period of May 15, 2000 and Nov 21, 2000 that discuss/show the element of claiming invention.

11. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claim Objections

Claims 29 and 30 are objected to because of the following informalities: Claim 29 and 30 apparently to improperly depends on Claims 24 and 25. The Claims 29 and 30 should appear to be depending on methods claims such as Claims 1 or 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21, 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatts (US 3,675,640) in view of Menzie et al (US 6,650,932) in further view of Lin (US 5,835, 384).

14. Referring to Claims 1, 11, 19, 24, 25, and 26-30, Gatts discloses a method of collecting and reporting outcomes data for benchmarking medical procedures comprising the steps of:

at least one processor readable medium (computer 44, refer to Col 7, Lines 24);

instructions carried on the at least one processor readable medium (computer 44, refer to Col 7, Lines 24);

wherein the instructions are configured to be readable from the at least one processor readable medium by at least one processor and thereby cause the at least one processor to operate (computer, refer to Col 7, Lines 24) so as to:

collecting first outcomes data sets for one or more indicators associated with one or more medical procedures (records test data, refer to Abstract, the data is in the form of the significant parameters/indicators of the medical procedures, such as cardiac, pulmonary, and physical characteristics, refer to Col 1, Lines 35-40) for a plurality of patients (large numbers of individuals) in a first period of time (during the time when the data are collected) via one or more user interface (data is extracted from the sensor/interface on the exercising machine, refer to abstract and Col 2, Lines 5) located at one or more user entities (sensors located on the machine location of the clinic, refer to abstracts);

establishing a norm based at least in part on an outcomes data group (establish norm, refer to abstract), the outcomes data group comprising a plurality of the first outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals (see abstracts);

collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the individual in a second period of time via the

one or more user interface located at the one or more user entities (collects the information associated with medical procedures from the patient, refer to Col 7, Lines 12-19 during a period of the time after the norm is established, refer to Col 7, Lines 36 at a clinic);

converting at least some of the second outcomes data sets (one data set) for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals into at least one outcomes result (data collected are converted into curve, refer to Col 7, Lines 56);

comparing a selected one of the at least one outcomes result to the norm (refer to Col 7, Lines 29-35); and

generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (printout the results vs the norm, refer to Col 7, Lines 29-60);

wherein the one or more indicators including at least one of verbal responses, measured analytical data, and observation of a third-party observer (refer to Col 6, Lines 70-75);

Although Gatts disclosed the invention substantially as claimed, Gatts is silent in regarding "the second outcomes data sets are collected from plurality of individuals."

Menzie, discloses a similar teaching of collecting data associated with medical procedures comprising: "collecting second outcomes data sets are collected from a plurality individuals (each collecting devices located at different medical facility, refer to Col 3, Lines 65-67. Each device collects patients' medical condition information Col 2, Lines 10-11 and analyzes the data to provide the test result (convert the second outcomes data), refer to Col 2, Lines Col 15-18)."

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine Gatts and Menzie because Menzie's teaching of "collecting second outcomes data sets are collected from a plurality individuals" would improve Gatts's system by efficiently collect medical data from geographically dispersed devices and process it in the efficient manner (supported by Lin Col 2, lines 60-67).

15. Referring to Claims 2 and 12, Gatts discloses transmitting the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals to a data processor (refer to abstracts and to Col 7, Lines 23-35).

16. Referring to Claims 3, 5, 13, 15, and 21, although Gatt disclosed the invention substantially as claimed, Gatt is silent in regarding "selectively restricting access to the at least one outcomes monitoring report"

Menzie, discloses a similar teaching of collecting data associated with medical procedures comprising: "selectively restricting access to the at least one outcomes monitoring report (refer to Col 11, Lines 5-30)."

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine Gatts and Menzie because Menzie's teaching of "collecting second outcomes data sets are collected from a plurality individuals" would improve Gatts's system by efficiently collect medical data from geographically dispersed devices and process it in the efficient manner (supported by Lin Col 2, lines 60-67).

17. Referring to Claims 4, and 14 and 20, although Gatt disclosed the invention substantially as claimed, Gatt is silent in regarding "posting the at least one outcomes monitoring report over the webpage".

Menzie, discloses a similar teaching of collecting data associated with medical procedures comprising: "posting the at least one outcomes monitoring report over the webpage (refer to Col 4, Lines 14)."

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine Gatts and Menzie because Menzie's teaching of "collecting second outcomes data sets are collected from a plurality individuals" would improve Gatts's system by efficiently collect medical data from geographically dispersed devices and process it in the efficient manner (supported by Lin Col 2, lines 60-67).

18. Referring to Claim 6, Gatt discloses collecting first and second outcomes data sets associated with the one or more medical procedures from at least one user entity at a plurality of discrete intervals (see abstracts and Col 7, Lines 22-65).

19. Referring to Claim 7, Gatt discloses generating the at least one outcomes monitoring report from the plurality of discrete intervals (refer to 35-40).

20. Referring to Claims 8 and 16, Gatt discloses collecting the second outcomes data sets for the one or more indicators associated with the one or more medical procedures for the individual

located at the one or more user entities (collects the information associated with medical procedures from the patient, refer to Col 7, Lines 12-19 during a period of the time after the norm is established, refer to Col 7, Lines 36),

individually identifying and converting the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at each user entity of the one or more entities (data collected are converted into curve, refer to Col 7, Lines 56),

and wherein the second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the individual located at the one or more user entities comprises the outcomes data group (collects the information associated with medical procedures from the patient, refer to Col 7, Lines 12-19 during a period of the time after the norm is established, refer to Col 7, Lines 36 at a clinic).

Although Gatts disclosed the invention substantially as claimed, Gatts is silent in regarding "the second outcomes data sets are collected from plurality of individuals."

Menzie, discloses a similar teaching of collecting data associated with medical procedures comprising: "collecting second outcomes data sets are collected from a plurality individuals (each collecting devices located at different medical facility, refer to Col 3, Lines 65-67. Each device collects patients' medical condition information Col 2, Lines 10-11 and analyzes the data to provide the test result (convert the second outcomes data), refer to Col 2, Lines Col 15-18)."

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine Gatts and Menzie because Menzie's teaching of "collecting second

outcomes data sets are collected from a plurality individuals" would improve Gatts's system by efficiently collect medical data from geographically dispersed devices and process it in the efficient manner (supported by Lin Col 2, lines 60-67).

21. Referring to Claim 9 and 17, Gatt discloses wherein the at least one outcomes monitoring report includes the at least one outcomes result for a selected user entity of the one or more user entities and at least one comparison of the norm to the least one outcomes result for the selected user entity (printout the results vs the norm, refer to Col 7, Lines 29-60).

22. Referring to Claims 10, and 18, Gatt discloses at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1 (computer, refer to Col 7, Lines 24).

23. Referring to Claim 23, Gatt discloses wherein the first and second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals are primary source data sets (refer to abstracts).

Conclusion

Examiner's Notes: Examiner has cited particular columns and line numbers in the references applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to specific

limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner. In the case of amending the claimed invention, Applicant is respectfully requested to indicate the portion(s) of the specification which dictate(s) the structure relied on for proper interpretation and also to verify and ascertain the metes and bounds of the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen C. Tang whose telephone number is (571)272-3116. The examiner can normally be reached on M-F 7 - 3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Follansbee can be reached on (571)272-3964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. C. T./
Examiner, Art Unit 2451

/John Follansbee/ SPE 2451